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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,206	12/21/2001	Nisar Ahmed Khan	2183-5222US	5353

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SALT LAKE CITY, UT 84110

EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/029,206	Applicant(s) KHAN ET AL.	
	Examiner Jean C. Witz	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 16-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 21, 2005 have been fully considered but they are not persuasive for the reasons set forth below.

Election/Restrictions

2. Applicant's election with traverse of the species of infection with pathogenic bacteria in the reply filed on March 21, 2005 is acknowledged. The traversal is on the ground(s) that that a reasonable number of species were included in the application. This is not found persuasive because the species of conditions were extensive and diverse. Since the elected invention was a method and a required search includes numerous and varied databases as well as a class and subclass search, there would be a substantial burden on the Examiner to examine other species of conditions. Other than an assertion that the number of species was reasonable, no other arguments or evidence was presented by Applicants.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. Claims 1-8, 10-12, 16-18 and 20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Via their statements, Applicants appear to be asserting that, as a result of the amendments to the claims whereby the inflammation to be mediated is the NFKappaB mediated inflammation, the claims are fully enabled by the specification. Applicants state that the references provided by the Examiner relate to the activity of the lethal toxin (aka lethal factor) released by the anthrax bacteria. This statement appears to be implying that the inflammatory pathogenesis is not affected by the lethal toxin and that amelioration of the inflammatory pathogenesis will predictably result in treatment of an anthrax infection. Applicants' statements have failed to provide evidence of predictability in the treatment of pathogenic infections and specifically anthrax.

First, it is noted that known antibiotics have limited efficacy after the bacteria produce a threshold toxin level. Reduction of bacterial load is ineffective if a threshold amount of toxin has been produced and released. See Kalns et al., BBRC 297: 506-509 (2002). It remains unclear and unpredictable as to the relationship between the timing and effect of the NFKappaB-mediated inflammation and the timing and effect of the release of the lethal toxin. As a result, it is unclear and unpredictable that any treatment of the NFKappaB-mediated inflammation will have any meaningful treatment of the condition of anthrax or any other pathogenic bacterial infection.

Second, references to Kalns et al., BBRC 292: 41-44 (2002) and Pellizzari et al. (FEBS Letters 462: 199-204 (1999) indicate that attenuated immune responses increases the rate of disease progression. Applicants' attention is particularly directed to the disclosure of Pellizzari et al. which addresses the

Art Unit: 1651

activity of the lethal factor in cleaving MAPKK enzymes and that LF inhibits the release of TNFa and NO. These results were concluded to be advantageous to the growth of the bacterium during the initial phase of infection. Since Applicants suggest at page 13 of the specification that the oligopeptide used in the practice of the claimed invention be a fragment of MAPKK, it remains unclear and unpredictable as to whether the lethal factor will cleave the oligopeptide and therefore render it ineffective. Further, the result of the treatment of the subject with the oligopeptide is disclosed and claimed to result in the reduction of both TNFa and NO in the subject. It also remains unclear and unpredictable as to whether this reduction will provide a beneficial effect in view of the conclusion of Pellizzari et al. that reductions in TNFa and NO in a subject suffering from an infection of *Bacillus anthracis* act to benefit the organism and not the subject. Since Kalns et al. (BBRC 297) suggest that the point where the lethal toxin burden becomes lethal may occur prior to presentation of clinical symptoms, it remains unclear and unpredictable as to whether the claimed invention would actually treat versus accelerate the disease progression and ultimate outcome.

Applicants' remarks regarding the government regulations governing the use of anthrax for experimentation are acknowledged, these limitations cannot be given priority over the patent statutes.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1651

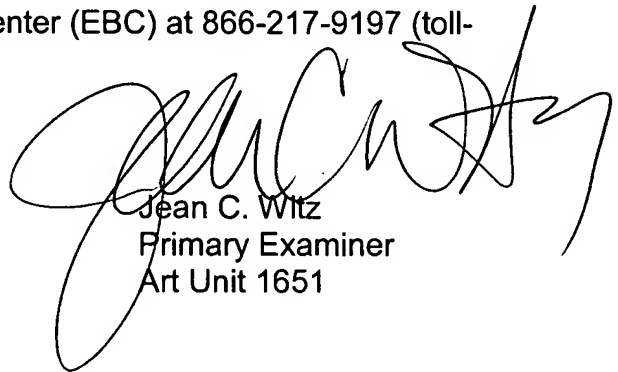
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz
Primary Examiner
Art Unit 1651